



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,856	10/27/2003	Robert Yongxin	A8671	9247
23373	7590	03/29/2005	EXAMINER	
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			SHIAO, REI TSANG	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/692,856

Applicant(s)

YONGXIN ET AL.

Examiner

Robert Shiao

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on responses filed on 1/31, 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9, 11 and 23-31 is/are pending in the application.
- 4a) Of the above claim(s) 23, 24, 26 and 27 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7-9, 11 and 23-31 is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Amendment of claim 1, 4, 7, 25, cancellation of claims 10, 12-22, addition of claims 29-31, a declaration (Rule 1.131 or 132) in the amendment filed on January 31, 2005, is acknowledged. No new matter is found. Claims 1-9, 11, 23-31 are pending in the application. Since the newly added claims 29-31 are commensurate with the scope of instant invention, therefore, claims 1-9, 11, 23-31 are prosecuted in the case.

#### ***Responses to Amendment/Arguments***

2. Since the limitation "comprising" has been eliminated from claims 1 and 7 respectively, therefore, rejection of claims 1-9, 11, 25, and 28 under 35 U.S.C. 112, second paragraph, has been overcome in the amendment filed on January 31, 2005. Since claims 10 and 12-22 have been cancelled, therefore, rejection of claims 10 and 12-22 under 35 U.S.C. 112, second paragraph, is obviated herein.

#### ***Responses to Arguments***

3. Applicant's arguments regarding rejection of claims 1-6 under 35 U.S.C. 112, first paragraph, filed on January 31, 2005, have been fully considered but they are not persuasive. Applicants argue that (1) instant claims are entitled to claim prodrug of any analog of CC-1065; (2) the application contains a written description of a board group of CC-1065 analogs and prodrug thereof; (3) the application teaches one of ordinary skill in the art how to make

Art Unit: 1626

and use a board group of CC-1065 analogs and prodrug thereof, also see applicant's declaration filed on January 31, 2005. It is noted that CC-1065 analogs have been described thus far are quite unstable in aqueous solution, thus, there is a need to protect the reactive portion of CC-1065 analogs in order to extend their useful life in aqueous solution, see page 5, lines 9-15 of the specification. Therefore, applicant's arguments are self-conflict, and any analog of CC-1065 (i.e., formula of Fig 1B or 1C or their related moieties) are quite unstable in aqueous solution, and not suitable for prodrugs. Moreover, applicants do not clearly point out substantial or specific written description (i.e., a specific compounds/analog of CC-1065 having specific formulae) for enablement for a prodrug other than a first subunit of formula (I) covalently linked to a second subunit of formula (II)-(IX) in the specification. Therefore, one of ordinary skill in the art does not know how to make or use CC-1065 analogs and prodrug other than compounds of formula (I), and (II)-(IX) without undue experimentation. Rejection of claims 1-6 under 35 U.S.C. 112, first paragraph, is maintained. Since claims 10 and 12-22 have been cancelled, therefore, rejection of claims 10 and 12-22 under 35 U.S.C. 112, first paragraph, is obviated herein.

Incorporation of the limitation of "a compound prodrug of an analog of CC-1065", i.e., formula (I) and (V) and their covalent linking positions between formula (I) and (V), the limitation of the variable R<sub>7</sub> (i.e., piperazino carbamate or 4-piperidino-piperidino carbamate) of formula (I), and limitation of variable R, R<sub>1</sub>-R<sub>6</sub> of formula (V), would obviate the rejection, see pages 7-10 of the specification.

Art Unit: 1626

4. Claims 7-9, 11, 23-31 are neither anticipated nor rendered obvious over the art of record, and therefore are allowable. This invention relates to prodrug of CC-1065 analogs.

***Objection***

5. Claims 23-24 and 26-27 are objected to as belonging to a non-elected invention. Elimination of claims 23-24 and 26-27 would obviate the objection.

6. Claims 1-6 are objected to as containing non-elected subject matter. It is suggested that applicants amend the claims to the scope of the elected subject matter as defined on the elected subject matter of the third paragraph of the previous Office Action, dated October 21, 2004.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1626

***Telephone Inquiry***

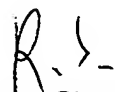
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707.

The examiner can normally be reached on 8:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Rita Desai  
Primary Patent Examiner  
Technical Center 1600  
Tel: (571) 272-0684



Robert Shiao, Ph.D.  
Patent Examiner  
Art Unit 1626

March 23, 2005

3/23/05